

1 AMY W. SCHULMAN  
2 DLA PIPER LLP  
3 1251 Avenue of the Americas  
4 New York, NY 10020  
5 Telephone: (212) 335-4500  
6 Facsimile: (212) 335-4501  
7 amy.schulman@dlapiper.com

5 STUART M. GORDON (SBN: 037477)  
6 GORDON & REES LLP  
7 Embarcadero Center West  
8 275 Battery Street, Suite 2000  
9 San Francisco, CA 94111  
Telephone: (415) 986-5900  
Facsimile: (415) 986-8054  
sgordon@gordonrees.com

10 MICHAEL C. ZELLERS (SBN: 146904)  
11 TUCKER ELLIS & WEST LLP  
12 515 South Flower Street, Suite 4200  
13 Los Angeles, CA 90071-2223  
14 Telephone: (213) 430-3400  
15 Facsimile: (213) 430-3409  
16 [michael.zellers@tuckerellis.com](mailto:michael.zellers@tuckerellis.com)

14 Attorneys for Defendants  
PFIZER INC., PHARMACIA CORPORATION, AND  
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

19 IN RE CELEBREX AND BEXTRA ) MDL Docket No. 1699  
20 MARKETING, SALES PRACTICES AND )  
21 PRODUCTS LIABILITY LITIGATION ) CASE NO. 3:07-cv-6509-CRB  
22 *This document relates to* )  
23 OLLIE STEWART, et al., )  
24 Plaintiffs, )  
25 vs. )  
26 PFIZER, INC., PHARMACIA CORPORATION, )  
27 and G.D. SEARLE, LLC, )  
Defendants. )  
PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE, LLC'S ANSWER TO COMPLAINT  
JURY DEMAND ENDORSED HEREIN

2 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
3 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC  
4 (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively  
5 "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would  
respectfully show the Court as follows:

L.

## **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used  
9 Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally.  
10 Defendants may seek leave to amend this Answer when discovery reveals the specific time  
11 periods in which Plaintiffs were prescribed and used Bextra®.

II.

## ANSWER

## **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but  
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States  
18 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
20 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,  
21 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare  
22 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
23 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,  
28 and deny the remaining allegations in this paragraph of the Complaint.

1 2. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.

3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 3. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.

6 Defendants deny the remaining allegations in this paragraph of the Complaint.

7 4. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.

9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 5. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.

12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13 6. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
14 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
15 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
16 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted  
17 Bextra® in the United States, including California and Mississippi, to be prescribed by  
18 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
19 approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in  
20 interest" are vague and ambiguous. Defendants are without knowledge or information to form  
21 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the  
22 remaining allegations in this paragraph of the Complaint.

23 7. Defendants admit that Searle is a Delaware limited liability company with its principal  
24 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®  
25 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted  
26 and distributed Bextra® in the United States to be prescribed by healthcare providers who are  
27 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
28 deny the remaining allegations in this paragraph of the Complaint.

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1 8. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
2 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia  
3 marketed and co-promoted Bextra® in the United States, including California, Michigan, and  
4 Illinois, to be prescribed by healthcare providers who are by law authorized to prescribe drugs  
5 in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations  
6 regarding "predecessors in interest" are vague and ambiguous. Defendants are without  
7 knowledge or information to form a belief as to the truth of such allegations, and, therefore,  
8 deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

## **Response to Allegations Regarding Jurisdiction and Venue**

10. Defendants are without knowledge or information to form a belief as to the truth of the  
11 allegations in this paragraph of the Complaint regarding the amount in controversy, and,  
12 therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount  
13 in controversy exceeds \$75,000, exclusive of interests and costs.

14 10. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and  
16 the amount in controversy, and, therefore, deny the same. However, Defendants admit that  
17 Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000,  
18 exclusive of interests and costs.

19 11. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding the judicial district in  
21 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny  
22 committing a tort in the States of California and Mississippi and deny the remaining allegations  
23 in this paragraph of the Complaint.

24 12. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
25 and co-promoted Bextra® in the United States, including California and Michigan, to be  
26 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
27 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®  
28 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted

1 and distributed Bextra® in the United States to be prescribed by healthcare providers who are  
2 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
3 admit that they provided FDA-approved prescribing information regarding Bextra®.  
4 Defendants admit that they do business in the State of California. Defendants state that  
5 Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous.  
6 Defendants are without knowledge or information to form a belief as to the truth of such  
7 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
8 remaining allegations in this paragraph of the Complaint.

9 **Response to Allegations Regarding Interdistrict Assignment**

10 13. Defendants state that this paragraph of the Complaint contains legal contentions to  
11 which no response is required. To the extent that a response is deemed required, Defendants  
12 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
13 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
14 Panel on Multidistrict Litigation on September 6, 2005.

15 **Response to Factual Allegations**

16 14. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
18 Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiffs injury  
19 or damage, and deny the remaining allegations in this paragraph of the Complaint.

20 15. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
22 Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury  
23 or damage, and deny the remaining allegations in this paragraph of the Complaint.

24 16. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
26 Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury  
27 or damage, and deny the remaining allegations in this paragraph of the Complaint.

28 17. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used  
2 Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury  
3 or damage, and deny the remaining allegations in this paragraph of the Complaint.

4 18. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding Plaintiffs' medical condition and whether Plaintiffs used  
6 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
7 Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 19. Defendants admit that Bextra® was expected to reach consumers without substantial  
10 change from the time of sale. Defendants are without knowledge or information sufficient to  
11 form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and,  
12 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the  
13 Complaint.

14 20. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
19 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.  
20 Defendants deny remaining the allegations in this paragraph of the Complaint.

21 21. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-  
22 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe  
23 and effective when used in accordance with its FDA-approved prescribing information.  
24 Defendants state that the potential effects of Bextra® were and are adequately described in its  
25 FDA-approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny the remaining allegations in this  
27 paragraph of the Complaint.

28 22. The allegations in this paragraph of the Complaint are not directed toward Defendants

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1 and, therefore, no response is required. To the extent a response is deemed required,  
2 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
3 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
4 form a belief as to the truth of such allegations and, therefore, deny the same.

5 23. The allegations in this paragraph of the Complaint are not directed toward Defendants  
6 and, therefore, no response is required. To the extent a response is deemed required,  
7 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
8 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
9 form a belief as to the truth of such allegations and, therefore, deny the same.

10 24. The allegations in this paragraph of the Complaint are not directed toward Defendants  
11 and, therefore, no response is required. To the extent a response is deemed required,  
12 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
13 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
14 form a belief as to the truth of such allegations and, therefore, deny the same.

15 25. The allegations in this paragraph of the Complaint are not directed toward Defendants  
16 and, therefore, no response is required. To the extent a response is deemed required,  
17 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this  
18 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
19 form a belief as to the truth of such allegations and, therefore, deny the same.

20 26. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
21 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth  
22 of such allegations and, therefore, deny the same.

23 27. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are  
24 vague and ambiguous. Defendants are without knowledge or information to form a belief as to  
25 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful  
26 conduct and deny the remaining allegations in this paragraph of the Complaint.

27 28. Plaintiffs do not allege having used Celebrex® in this Complaint. Nevertheless,  
28 Defendants admit that Celebrex® was launched in the United States in February 1999.

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1 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
2 FDA-approved prescribing information. Defendants admit that, during certain periods of time,  
3 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
5 with their approval by the FDA. Defendants admit that, during certain periods of time,  
6 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
7 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
8 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
9 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not  
10 directed toward Defendants and, therefore, no response is required. To the extent a response is  
11 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
12 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants  
13 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
14 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this  
15 paragraph of the Complaint.

16 29. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
17 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the  
18 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis  
19 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.  
20 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
21 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
22 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in  
23 this paragraph of the Complaint.

24 30. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.  
25 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is  
26 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
27 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining  
28 allegations in this paragraph of the Complaint.

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1 31. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
2 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
3 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny  
4 the remaining allegations in this paragraph of the Complaint.

5 32. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
6 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
7 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
8 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
9 prescribing information. Defendants state that the potential effects of Bextra® were and are  
10 adequately described in its FDA-approved prescribing information, which at all times was  
11 adequate and comported with applicable standards of care and law. Defendants deny the  
12 remaining allegations in this paragraph of the Complaint.

13 33. Defendants state that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information,  
16 which at all times was adequate and comported with applicable standards of care and law.  
17 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
18 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
20 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
21 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
22 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
23 with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding  
24 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
25 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 34. Defendants state that the referenced article speaks for itself and respectfully refer the

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1 Court to the article for its actual language and text. Any attempt to characterize the article is  
2 denied. Defendants state that Bextra® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
4 this paragraph of the Complaint.

5 35. The allegations in this paragraph of the Complaint are not directed towards Defendants  
6 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
7 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
8 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
9 the remaining allegations in this paragraph of the Complaint.

10 36. Defendants admit that the New Drug Application for Bextra® was filed with the FDA  
11 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November  
12 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this  
13 paragraph of the Complaint.

14 37. Defendants state that Bextra® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Bextra® were and are adequately described in its FDA-approved prescribing information,  
17 which at all times was adequate and comported with applicable standards of care and law.  
18 Defendants deny the allegations in this paragraph of the Complaint.

19 38. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and  
20 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to  
21 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this  
22 paragraph of the Complaint.

23 39. Defendants state that the referenced article speaks for itself and respectfully refer the  
24 Court to the article for its actual language and text. Any attempt to characterize the article is  
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 40. Plaintiffs fail to provide the proper context for the allegations concerning the “post-drug  
27 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without  
28 sufficient information to confirm or deny such allegations and, therefore, deny the same.

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1 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
2 the study for its actual language and text. Any attempt to characterize the study is denied.

3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 41. The allegations in this paragraph of the Complaint are not directed towards Defendants  
5 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
6 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
7 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
8 the remaining allegations in this paragraph of the Complaint.

9 42. The allegations in this paragraph of the Complaint are not directed towards Defendants  
10 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
11 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk  
12 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the  
13 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its  
14 actual language and text. Any attempt to characterize the testimony is denied. Defendants  
15 deny the remaining allegations in this paragraph of the Complaint.

16 43. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
18 deny the remaining allegations in this paragraph of the Complaint.

19 44. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
20 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
21 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
22 Defendants deny the remaining allegations in this paragraph of the Complaint.

23 45. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
24 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
25 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 46. Defendants state that Bextra® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants deny the allegations in this

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1 paragraph of the Complaint.

2 47. Defendants state that the referenced article speaks for itself and respectfully refer the  
3 Court to the article for its actual language and text. Any attempt to characterize the article is  
4 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
5 paragraph of the Complaint.

6 48. The allegations in this paragraph of the Complaint are not directed towards Defendants  
7 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants  
8 state that the referenced article speaks for itself and respectfully refer the Court to the article for  
9 its actual language and text. Any attempt to characterize the article is denied. Defendants deny  
10 the remaining allegations in this paragraph of the Complaint.

11 49. Defendants state that Bextra® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants state that the potential effects of  
13 Bextra® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.  
15 Defendants deny the allegations in this paragraph of the Complaint.

16 50. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 51. Defendants state that Bextra® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Bextra® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 52. Defendants deny the allegations in this paragraph of the Complaint.

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1 53. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
2 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
3 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
4 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
5 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
6 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
7 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 state that the potential effects of Bextra® were and are adequately described in its FDA-  
10 approved prescribing information, which was at all times adequate and comported with  
11 applicable standards of care and law. Defendants are without knowledge or information  
12 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used  
13 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
14 allegations in this paragraph of the Complaint.

15 54. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
16 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
17 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
18 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
19 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
20 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
21 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Bextra® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny the remaining allegations in this  
26 paragraph of the Complaint.

27 55. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
28 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
2 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
3 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
4 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
5 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
6 effective when used in accordance with its FDA-approved prescribing information. Defendants  
7 state that the potential effects of Bextra® were and are adequately described in its FDA-  
8 approved prescribing information, which was at all times adequate and comported with  
9 applicable standards of care and law. Defendants admit, as indicated in the package insert  
10 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms  
11 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary  
12 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 56. Defendants state that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information,  
16 which at all times was adequate and comported with applicable standards of care and law.  
17 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
18 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
19 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny  
20 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

21 57. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
22 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
23 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
24 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
25 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
26 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
27 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and  
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Bextra® were and are adequately described in its FDA-  
2 approved prescribing information, which was at all times adequate and comported with  
3 applicable standards of care and law. Defendants deny the remaining allegations in this  
4 paragraph of the Complaint.

5 58. Defendants state that Bextra® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Bextra® were and are adequately described in its FDA-approved prescribing information,  
8 which at all times was adequate and comported with applicable standards of care and law.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 59. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint.

16 60. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 61. Defendants deny the allegations in this paragraph of the Complaint.

23 62. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market  
24 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations  
25 contained in this paragraph of the Complaint.

26 63. Defendants state that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
3 allegations in this paragraph of the Complaint.

4 64. Defendants state that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 65. Defendants deny any wrongful conduct and deny the remaining allegations in this  
11 paragraph of the Complaint.

12 66. Defendants state that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
17 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
19 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
20 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
21 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
22 with their approval by the FDA. Defendants deny any wrongful conduct and deny the  
23 remaining allegations in this paragraph of the Complaint.

24 67. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
25 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
26 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
27 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
28 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to

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1 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
2 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
3 paragraph of the Complaint.

4 68. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
5 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
6 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
7 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
8 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
9 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
10 accordance with their approval by the FDA. Defendants admit, as indicated in the package  
11 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and  
12 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of  
13 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining  
14 allegations in this paragraph of the Complaint.

15 69. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants are without knowledge or information sufficient to form a belief as to the truth of  
20 the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same.  
21 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
22 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
23 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny  
24 that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the  
25 remaining allegations in this paragraph of the Complaint.

26 **Response to First Cause of Action: Negligence**

27 70. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
28 Complaint as if fully set forth herein.

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1 71. Defendants state that this paragraph of the Complaint contains legal contentions to  
2 which no response is required. To the extent a response is deemed required, Defendants admit  
3 that they had duties as are imposed by law but deny having breached such duties. Defendants  
4 state that the potential effects of Bextra® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants state that Bextra® was and is safe and  
7 effective when used in accordance with its FDA-approved prescribing information. Defendants  
8 deny the remaining allegations in this paragraph of the Complaint.

9 72. Defendants state that this paragraph of the Complaint contains legal contentions to  
10 which no response is required. To the extent a response is deemed required, Defendants admit  
11 that they had duties as are imposed by law but deny having breached such duties. Defendants  
12 state that Bextra® was and is safe and effective when used in accordance with its FDA-  
13 approved prescribing information. Defendants deny the remaining allegations in this paragraph  
14 of the Complaint.

15 73. Defendants state that this paragraph of the Complaint contains legal contentions to  
16 which no response is required. To the extent that a response is deemed required, Defendants  
17 admit that they had duties as are imposed by law but deny having breached such duties.  
18 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
19 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
20 were and are adequately described in its FDA-approved prescribing information, which was at  
21 all times adequate and comported with applicable standards of care and law. Defendants deny  
22 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,  
23 including all subparts.

24 74. Defendants state that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Bextra® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants are without knowledge or information sufficient to form a belief as to the truth of

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1 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.  
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
3 the Complaint.

4 75. Defendants state that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 76. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny  
12 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this  
13 paragraph of the Complaint.

14 77. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 78. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
17 damage and deny the remaining allegations in this paragraph of the Complaint.

18 79. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 **Response to Second Cause of Action: Strict Liability**

21 80. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
22 Complaint as if fully set forth herein.

23 81. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
25 same. Defendants admit that Bextra® was expected to reach consumers without substantial  
26 change in the condition from the time of sale. Defendants admit that, during certain periods of  
27 time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be  
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

1 with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra®  
2 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted  
3 and distributed Bextra® in the United States to be prescribed by healthcare providers who are  
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
5 state that Bextra® was and is safe and effective when used in accordance with its FDA-  
6 approved prescribing information. Defendants state that the potential effects of Bextra® were  
7 and are adequately described in its FDA-approved prescribing information, which was at all  
8 times adequate and comported with applicable standards of care and law. Defendants deny the  
9 remaining allegations in this paragraph of the Complaint.

10 82. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny the allegations in this paragraph of the Complaint.

15 83. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining  
20 allegations in this paragraph of the Complaint.

21 84. Defendants state that this paragraph of the Complaint contains legal contentions to  
22 which no response is required. To the extent a response is deemed required, Defendants state  
23 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
24 prescribing information. Defendants state that the potential effects of Bextra® were and are  
25 adequately described in its FDA-approved prescribing information, which was at all times  
26 adequate and comported with applicable standards of care and law. Defendants deny that  
27 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the  
28 Complaint, including all subparts.

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1 85. Defendants state that this paragraph of the Complaint contains legal contentions to  
2 which no response is required. To the extent a response is deemed required, Defendants state  
3 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
4 prescribing information. Defendants state that the potential effects of Bextra® were and are  
5 adequately described in its FDA-approved prescribing information, which was at all times  
6 adequate and comported with applicable standards of care and law. Defendants deny any  
7 wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining  
8 allegations in this paragraph of the Complaint.

9 86. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®  
14 caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the  
15 Complaint.

16 87. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 88. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
24 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Bextra® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-

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1 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law  
2 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
3 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which  
4 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be  
5 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
6 with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is  
7 defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining  
8 allegations in this paragraph of the Complaint.

9 89. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 90. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
16 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 91. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
23 deny the remaining allegations in this paragraph of the Complaint.

24 92. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
26 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph  
3 of the Complaint.

4 93. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 94. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 95. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Third Cause of Action: Breach of Express Warranty**

11 96. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 97. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
15 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Bextra® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants admit that they provided FDA-approved prescribing information regarding  
20 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 98. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
23 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Bextra® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants admit that they provided FDA-approved prescribing information regarding  
28 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint,

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1 including all subparts.

2 99. Defendants deny the allegations in this paragraph of the Complaint.

3 100. Defendants state that Bextra® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Bextra® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants admit that they provided FDA-approved prescribing information regarding  
8 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 101. Defendants state that Bextra® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Bextra® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants admit that they provided FDA-approved prescribing information regarding  
14 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of  
15 the Complaint.

16 102. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
18 same. Defendants admit that they provided FDA-approved prescribing information regarding  
19 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 103. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 104. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 105. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Fourth Cause of Action: Breach of Implied Warranty**

27 106. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
28 Complaint as if fully set forth herein.

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1 107. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
2 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are  
3 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
4 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
5 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
6 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
7 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
8 paragraph of the Complaint.

9 108. Defendants admit that they provided FDA-approved prescribing information regarding  
10 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that  
11 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
12 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state  
13 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
14 prescribing information. Defendants deny the remaining allegations in this paragraph of the  
15 Complaint.

16 109. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
18 same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®  
19 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
20 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny  
21 the remaining allegations in this paragraph of the Complaint.

22 110. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
24 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
26 this paragraph of the Complaint.

27 111. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the

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1 same. Defendants state that Bextra® was expected to reach consumers without substantial  
2 change in the condition from the time of sale. Defendants deny the remaining allegations in  
3 this paragraph of the Complaint.

4 112. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
6 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
8 deny the remaining allegations in this paragraph of the Complaint.

9 113. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 114. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
12 damage, and deny the remaining allegations in this paragraph of the Complaint.

13 115. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

16 116. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
17 Complaint as if fully set forth herein.

18 117. Defendants state that this paragraph of the Complaint contains legal contentions to  
19 which no response is required. To the extent a response is deemed required, Defendants admit  
20 that they had duties as are imposed by law but deny having breached such duties. Defendants  
21 state that Bextra® was and is safe and effective when used in accordance with its FDA-  
22 approved prescribing information. Defendants state that the potential effects of Bextra® were  
23 and are adequately described in its FDA-approved prescribing information, which was at all  
24 times adequate and comported with applicable standards of care and law. Defendants deny the  
25 remaining allegations in this paragraph of the Complaint.

26 118. Defendants state that Bextra® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
3 the Complaint, including all subparts.

4 119. Defendants state that Bextra® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Bextra® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 120. Defendants state that Bextra® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Bextra® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably  
15 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

16 121. Defendants state that Bextra® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Bextra® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 122. Defendants deny any wrongful conduct and deny the remaining allegations in this  
23 paragraph of the Complaint.

24 123. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
26 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
27 paragraph of the Complaint.

28 124. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
2 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
3 paragraph of the Complaint.

4 125. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
6 same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 126. Defendants deny any wrongful conduct and deny the remaining allegations in this  
9 paragraph of the Complaint.

10 127. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
12 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Bextra® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 129. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 130. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Sixth Cause of Action: Unjust Enrichment**

25 131. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
26 Complaint as if fully set forth herein.

27 132. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
28 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
2 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,  
3 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to  
4 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
6 paragraph of the Complaint.

7 133. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
9 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 134. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
12 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 135. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
15 same. Defendants state that Bextra® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
17 this paragraph of the Complaint.

18 136. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the  
20 same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 137. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Prayer for Relief**

25 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"  
26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,  
27 and deny the remaining allegations in this paragraph of the Complaint.

28 138. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 139. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 140. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 141. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 142. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 143. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 144. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 145. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or  
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 **III.**

17 **GENERAL DENIAL**

18 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'  
19 Complaint that have not been previously admitted, denied, or explained.

20 **IV.**

21 **AFFIRMATIVE DEFENSES**

22 Defendants reserve the right to rely upon any of the following or additional defenses to  
23 claims asserted by Plaintiffs to the extent that such defenses are supported by information  
24 developed through discovery or evidence at trial. Defendants affirmatively show that:

25 **First Defense**

26 1. The Complaint fails to state a claim upon which relief can be granted.

27 **Second Defense**

28 2. Bextra® is a prescription medical product. The federal government has preempted the

1 field of law applicable to the labeling and warning of prescription medical products.  
2 Defendants' labeling and warning of Bextra® was at all times in compliance with applicable  
3 federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon  
4 which relief can be granted; such claims, if allowed, would conflict with applicable federal law  
5 and violate the Supremacy Clause of the United States Constitution.

6 **Third Defense**

7 3. At all relevant times, Defendants provided proper warnings, information and  
8 instructions for the drug in accordance with generally recognized and prevailing standards in  
9 existence at the time.

10 **Fourth Defense**

11 4. At all relevant times, Defendants' warnings and instructions with respect to the use of  
12 Bextra® conformed to the generally recognized, reasonably available, and reliable state of  
13 knowledge at the time the drug was manufactured, marketed and distributed.

14 **Fifth Defense**

15 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the  
16 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

17 **Sixth Defense**

18 6. Plaintiffs' action is barred by the statute of repose.

19 **Seventh Defense**

20 7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the  
21 Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs'  
22 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory  
23 negligence and by the failure to mitigate damages.

24 **Eighth Defense**

25 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or  
26 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the  
27 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not  
28 liable in any way.

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## **Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

## **Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

## **Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

## Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

## **Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

## **Fourteenth Defense**

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

## **Fifteenth Defense**

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

## **Sixteenth Defense**

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

## **Seventeenth Defense**

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

## Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

## **Nineteenth Defense**

19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

## Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

## Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

## Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

### **Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary

1 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at  
 2 issue under applicable federal laws, regulations, and rules.

3 **Twenty-fourth Defense**

4 24. Plaintiffs' claims are barred in whole or in part because there is no private right of  
 5 action concerning matters regulated by the Food and Drug Administration under applicable  
 6 federal laws, regulations, and rules.

7 **Twenty-fifth Defense**

8 25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate  
 9 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning  
 10 of Comment j to Section 402A of the Restatement (Second) of Torts.

11 **Twenty-sixth Defense**

12 26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim  
 13 because Bextra® is a prescription pharmaceutical drug and falls within the ambit of  
 14 Restatement (Second) of Torts § 402A, Comment k.

15 **Twenty-seventh Defense**

16 27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical  
 17 product at issue "provides net benefits for a class of patients" within the meaning of Comment f  
 18 to § 6 of the Restatement (Third) of Torts: Products Liability.

19 **Twenty-eighth Defense**

20 28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
 21 Products Liability.

22 **Twenty-ninth Defense**

23 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead  
 24 facts sufficient under the law to justify an award of punitive damages.

25 **Thirtieth Defense**

26 30. The imposition of punitive damages in this case would violate Defendants' rights to  
 27 procedural due process under the Fourteenth Amendment of the United States Constitution and  
 28 the Constitution of the States of California and Mississippi, and would additionally violate

1 Defendants' right to substantive due process under the Fourteenth Amendment of the United  
2 States Constitution.

3 **Thirty-first Defense**

4 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and  
5 Fourteenth Amendments to the United States Constitution.

6 **Thirty-second Defense**

7 32. The imposition of punitive damages in this case would violate the First Amendment to  
8 the United States Constitution.

9 **Thirty-third Defense**

10 33. Plaintiffs' punitive damage claims are preempted by federal law.

11 **Thirty-fourth Defense**

12 34. In the event that reliance was placed upon Defendants' nonconformance to an express  
13 representation, this action is barred as there was no reliance upon representations, if any, of  
14 Defendants.

15 **Thirty-fifth Defense**

16 35. Plaintiffs failed to provide Defendants with timely notice of any alleged  
17 nonconformance to any express representation.

18 **Thirty-sixth Defense**

19 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without  
20 proof of causation, the claims violate Defendants' rights under the United States Constitution.

21 **Thirty-seventh Defense**

22 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and  
23 labeling with respect to the subject pharmaceutical products were not false or misleading and,  
24 therefore, constitute protected commercial speech under the applicable provisions of the United  
25 States Constitution.

26 **Thirty-eighth Defense**

27 38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly  
28 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable

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San Francisco, CA 94111

1 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process  
2 protections afforded by the United States Constitution, the excessive fines clause of the Eighth  
3 Amendment of the United States Constitution, the Commerce Clause of the United States  
4 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the  
5 Constitution of the States of California and Mississippi. Any law, statute, or other authority  
6 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially  
7 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient  
8 standards to guide and restrain the jury's discretion in determining whether to award punitive  
9 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate  
10 advance notice as to what conduct will result in punitive damages; (3) permits recovery of  
11 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or  
12 conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits  
13 recovery of punitive damages in an amount that is not both reasonable and proportionate to the  
14 amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5)  
15 permits jury consideration of net worth or other financial information relating to Defendants;  
16 (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict  
17 review of any punitive damages awards; (7) lacks constitutionally sufficient standards for  
18 appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court  
19 precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1  
20 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*  
21 *America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*,  
22 538 U.S. 408 (2003).

23 **Thirty-ninth Defense**

24 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
25 and marketing of Bextra®, if any, used in this case, included adequate warnings and  
26 instructions with respect to the product's use in the package insert and other literature, and  
27 conformed to the generally recognized, reasonably available, and reliable state of the  
28 knowledge at the time the product was marketed.

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San Francisco, CA 94111

## Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

## Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

## Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

### **Forty-third Defense**

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

## Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

## Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs.

## Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

## **Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

## Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

## **Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

## Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

## **Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

## **Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

## **Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act

1 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'  
 2 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the  
 3 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,  
 4 and with the specific determinations by FDA specifying the language that should be used in the  
 5 labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the  
 6 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
 7 United States.

8 **Fifty-fourth Defense**

9 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity  
 10 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

11 **Fifty-fifth Defense**

12 55. Defendants state on information and belief that the Complaint and each purported cause  
 13 of action contained therein is barred by the statutes of limitations contained in California Code  
 14 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as  
 15 may apply.

16 **Fifty-sixth Defense**

17 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
 18 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable  
 19 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against  
 20 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

21 **Fifty-seventh Defense**

22 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of  
 23 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil  
 24 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive  
 25 damages is also barred under California Civil Code § 3294(b).

26 **Fifty-eighth Defense**

27 58. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs'  
 28 claims are barred because Defendants did not make or breach any express or implied

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 San Francisco, CA 94111

1 warranties, Plaintiffs failed to give reasonable notice to Defendants of any alleged breach or  
2 breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

## Fifty-ninth Defense

4 59. Any verdict or judgment rendered against Defendants must be reduced under the laws of  
5 the State of Mississippi by those amounts which have been, or will, with reasonable certainty,  
6 replace or indemnify Plaintiffs, such as insurance, social security, worker's compensation, or  
7 employee benefits programs. Plaintiffs may have settled their claims for alleged injuries and  
8 damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the  
9 amount of any such settlement heretofore made between Plaintiffs and any such parties.

## **Sixtieth Defense**

1 60. Plaintiffs' claims for punitive damages are limited or barred by the standards governing  
2 exemplary damage awards which arise under the United States Constitution and decisions of  
3 the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589  
4 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and  
5 *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi  
6 Constitution, statutes, and decisions of Mississippi courts.

## **Sixty-first Defense**

18 61. Defendants assert that Plaintiffs' claim for punitive damages is governed and limited by  
19 Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the  
20 same.

## **Sixty-second Defense**

62. Bextra® and the Defendants' actions conformed to the state of the art medical and  
scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable  
product safety statutes and regulations as described in Restatement (Third) of Torts: Products  
Liability § 4.

### **Sixty-third Defense**

27 63. Defendants satisfied their duty to warn under the learned intermediary doctrine and  
28 Plaintiffs' claims are therefore barred.

## **Sixty-fourth Defense**

64. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

## Sixty-fifth Defense

65. Plaintiffs failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendants in any possible future litigation.

## Sixty-sixth Defense

66. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

## **Sixty-seventh Defense**

67. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

## Sixty-eighth Defense

68. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

## **Sixty-ninth Defense**

69. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

## **PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;

- 1 3. That Defendants be awarded their costs for this lawsuit;
- 2 4. That the trier of fact determine what percentage of the combined fault or other liability
- 3 of all persons whose fault or other liability proximately caused Plaintiffs' alleged
- 4 injuries, losses or damages is attributable to each person;
- 5 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
- 6 than an amount which equals their proportionate share, if any, of the total fault or other
- 7 liability which proximately caused Plaintiffs' injuries and damages; and
- 8 6. That Defendants have such other and further relief as the Court deems appropriate.

9 February 13, 2008

10 GORDON & REES LLP

11  
12 By: \_\_\_\_\_/s/  
13 Stuart M. Gordon  
14 sgordon@gordonrees.com  
15 Embarcadero Center West  
16 275 Battery Street, 20<sup>th</sup> Floor  
17 San Francisco, CA 94111  
18 Telephone: (415) 986-5900  
19 Fax: (415) 986-8054

20 February 13, 2008

21 TUCKER ELLIS & WEST LLP

22  
23 By: \_\_\_\_\_/s/  
24 Michael C. Zellers  
25 michael.zellers@tuckerellis.com  
26 515 South Flower Street, Suite 4200  
27 Los Angeles, CA 90071-2223  
28 Telephone: (213) 430-3400  
Fax: (213) 430-3409

29 Attorneys for Defendants  
30 PFIZER INC., PHARMACIA  
31 CORPORATION, AND G.D. SEARLE  
32 LLC

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a  
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil  
4 Procedure.

5 February 13, 2008

GORDON & REES LLP

6

7 By: \_\_\_\_\_/s/  
8 Stuart M. Gordon  
9 sgordon@gordonrees.com  
10 Embarcadero Center West  
11 275 Battery Street, 20<sup>th</sup> Floor  
12 San Francisco, CA 94111  
13 Telephone: (415) 986-5900  
14 Fax: (415) 986-8054

15 February 13, 2008

TUCKER ELLIS & WEST LLP

16 By: \_\_\_\_\_/s/  
17 Michael C. Zellers  
18 michael.zellers@tuckerellis.com  
19 515 South Flower Street, Suite 4200  
20 Los Angeles, CA 90071-2223  
21 Telephone: (213) 430-3400  
22 Fax: (213) 430-3409

23 Attorneys for Defendants  
24 PFIZER INC., PHARMACIA  
25 CORPORATION, AND G.D. SEARLE  
26 LLC

27 **Gordon & Rees, LLP**  
28 **275 Battery Street, Suite 2000**  
29 **San Francisco, CA 94111**